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10/625,232	07/22/2003	Nagy Adly Habib	380048-97	8627

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Attn: Barbara A. Wrigley  
OPPENHEIMER WOLFF & DONNELLY LLP  
45 South Seventh Street  
Suite 3300  
Minneapolis, MN 55402

EXAMINER
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ROANE, AARON F

ART UNIT	PAPER NUMBER
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3739

MAIL DATE	DELIVERY MODE
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01/18/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/625,232

Applicant(s)

HABIB ET AL.

Examiner

Aaron Roane

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 11/26/2007.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 12-19 and 25-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (USPN 5,472,441) in view of Edwards (USPN 5,836,906) in still further view of Swanson (USPN 6,267,760) and still in further view of Daniel et al. (USPN 7,008,421).

Regarding claims 1, 3, 5, 6, 12-14, 19 Edwards et al. disclose a device and method of treating tissue and/or an organ, the method comprising providing a device, the device comprising an applicator (222) having at least one face including an array of needles (215-219) each needle including a tissue-piercing distal tip (tissue piercing means), said array of needles arranged on said at least one face (distal face of 222 from through the needles pass) of the applicator, said applicator structured to be operably coupled to a source of electromagnetic energy; positioning said array of needles so that said array of needles surround a volume of tissue of tissue to be treated, said array of needles serving

to confine the electromagnetic energy field; extending the tissue-piercing distal tips of said array of needles from said at least one face of said applicator into said volume of tissue to be treated; applying said electromagnetic energy confined by the needles to the volume of the tissue to be treated; removing the tissue piercing distal tips of said array of needles from the volume of tissue to be treated, see 1-13 and more particularly col. 2, col.6-8 and col. 13, lines 53-60 and figures 1-16 and figure 16 in particular. Edwards et al. fail to explicitly disclose that the method is used to reduce bleeding and/or blood loss. Edwards et al. fail to explicitly disclose use of microwave but do disclose the known use on microwave energy to treat the tissue with the use of a cooling fluid to prevent undue damage, see col. 1, line 65 through col. 2, line 25. Additionally, Edwards et al. (Edwards I) fail to <sup>RWT</sup>~~disclose to~~ explicitly disclose the step of making an incision into the tissue which has been heated and advancing the applicator and extending the tissue-piercing distal tips along an incision line. Finally, Edwards et al. (Edwards I) fails to explicitly disclose bloodless resection of tissue. Applicant discloses on page 1, lines 10-15 that it is well known that heating tissue 20°C – 30°C greatly reduces blood flow. This great reduction in blood flow provides the inherent control of blood loss when tissue is heated. Edwards (Edwards II) discloses a tissue heating device having retractable needles (12) and teaches an alternative or equivalent energy delivery of microwave with cooling means and RF, see col. 1-7 and particularly col. 7, lines 28-38 and figures 1-6. Swanson discloses a device and method of heating tissue and teaches making an incision in the treated tissue after the heating step in order to reduce blood loss and verify the coagulation depth in the treated tissue, see col. 8, lines 33-41. Daniel et al. disclose a

device very similar to that of Edwards I and teach the method of heating the tissue sufficiently with the needles in order to bloodlessly resect tissue, see abstract, col. 2, line 63 through col. 3, line 65, col. 4-6. The present combination of the prior art meets the advancement of the applicator and extension of the array of needles along an incision line. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Edwards et al. (Edwards I), as is well known in the art, that blood flow in tissue is greatly reduced if the tissue is heated 20°C – 30°C, as further taught by Edwards (Edwards II), to use microwave (electromagnetic) energy as an alternate means of heating tissue, and as finally taught by Swanson, to make an incision in the heated tissue in order to reduce blood loss and verify the coagulation depth in the treated tissue and still as further taught by Daniel et al., to heat the tissue sufficiently with the needles in order to resect the tissue bloodlessly.

Regarding claims 2 and 4, Edwards et al. (Edwards I) in view of Edwards (Edwards II) in further view of Swanson and still in further view of Daniel et al. disclose the claimed invention, see Edwards II col. 6-9.

Regarding claims 15-18, 28-31 and 33-36, Edwards et al. (Edwards I) in view of Edwards (Edwards II) in further view of Swanson and still in further view of Daniel et al. disclose the claimed invention, see Edwards et al. col. 6-14 and figure 16.

Regarding claims 25-27, Edwards et al. (Edwards I) in view of Edwards (Edwards II) in further view of Swanson and still in further view of Daniel et al. disclose the claimed invention, see Edwards et al. figures 1-16.

Regarding claim 32, Edwards et al. (Edwards I) in view of Edwards (Edwards II) in further view of Swanson and still in further view of Daniel et al. disclose the claimed invention, see the conducting wires connected to the needles of (Edwards I) in figures 1-16.

Claims 7-11 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (USPN 5,472,441) in view of Edwards (USPN 5,836,906) in still further view of Swanson (USPN 6,267,760) and still in further view of Daniel et al. (USPN 7,008,421) as applied to claims 1, 3 and 6 above, and further in view of admitted prior art.

Regarding claims 7-11 and 20-24 Edwards et al. (Edwards I) in view of Edwards (Edwards II) in further view of Swanson and still in further view of Daniel et al. disclose the claimed invention in further view of Applicant's admission on the record that the claimed species are no patentably distinct as noted above.

*Response to Amendment*

The declaration under 37 CFR 1.132 filed 11/27/2007 (Affiant: Henri Bismuth) is insufficient to overcome the rejection of claims 1-36 based upon the rejections under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (USPN 5,472,441) in view of Edwards (USPN 5,836,906) in still further view of Swanson (USPN 6,267,760) and still in further view of Daniel et al. (USPN 7,008,421) as set forth in the last Office action because: the arguments present a method/sequence of combining the prior art of record that is not consistent with the of the present office action and the addition of newly recited claim language calls for a new grounds of rejection. Finally, the examiner believes Applicant interprets the recited phrase “applying said electromagnetic energy three-dimensionally” too narrowly. Applicant may be intending that the recited phrase “applying said electromagnetic energy three-dimensionally” be interpreted as that the needle array is three dimensional. However, this is not the case here. The examiner wishes to point out that “applying said electromagnetic energy three-dimensionally” is interpreted as that the needle array radiates energy in a three-dimensional pattern which is inherent. A single needle radiates energy in a three-dimensional pattern.

The declaration under 37 CFR 1.132 filed 11/14/2007 (Affiant: Victor Shevchenko) is insufficient to overcome the rejection of claims 1-36 based upon the rejections under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (USPN 5,472,441) in view of Edwards (USPN 5,836,906) in still further view of Swanson (USPN 6,267,760) and still in further view of Daniel et al. (USPN 7,008,421) as set forth in the last Office action because: the showing is not commensurate in scope with the claims. The claims of the presently claimed

invention are directed to a method of use. The support supposedly offered by the present declaration constitutes the estimated market share of the Habib device. Additionally, the parent case U.S. Patent 6,628,990 is directed to a device having an applicator with a waveguide (in the form of a resonance cavity) and retractable needles. The supposed evidence in the form of yearly (2005-2007) market share sales are estimates and based on the device not the method of use.

### *Response to Arguments*

Applicant's arguments with respect to claims 1-36 have been considered but are moot in view of the new ground(s) of rejection. The newly recited claim language "bloodlessly" resecting required the application of newly supplied prior art in the form of the Daniel et al. reference.

Additionally, it should be pointed out that Edwards I is the primary reference while, Edwards II, Swanson and Daniel et al. are all secondary (teaching) references.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Aaron Roane  
January 14, 2008

*A.R.*

*Roy D. Gibson*  
ROY D. GIBSON  
PRIMARY EXAMINER